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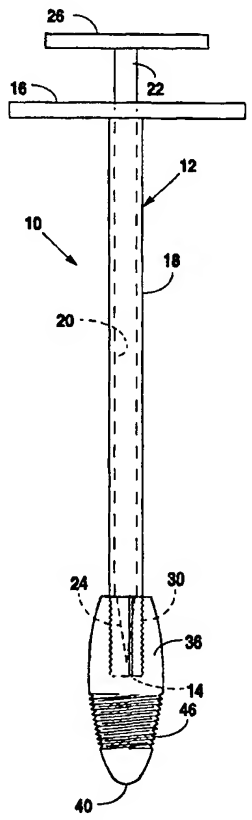
(57) Abstract

A middle expanded, removable disk implant for stabilizing adjacent vertebrae. The implant (14) is detachably mounted to an applicator (12) for insertion into the anatomical region between two adjacent vertebrae from which a portion of the intervertebral disk has been removed, and once inserted, is positioned by anterior-posterior movement in the disk space to the position in which both the expanded, larger diameter middle portion (44) and the smaller diameter end portions (40, 42) of the implant (14) engage the bodies of the adjacent vertebrae. Also provided is a method of lumbar intervertebral disk stabilization using a stabilizer (10) comprised of implant (14) and applicator (12).



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MIDDLE EXPANDED, REMOVABLE INTERVERTEBRAL DISK STABILIZER AND METHOD OF LUMBAR INTERVERTEBRAL DISK STABILIZATION

The present invention relates to an intervertebral disk stabilizing implant and a method of lumbar intervertebral disk stabilization ("LIDS"). More specifically, the present invention relates to cylindrically shaped disk implants which are expanded in the middle portion which are used for spinal fusion.

If the spine is injured or becomes diseased, surgical intervention involving removal of one or more disks, and fusion of the adjacent vertebrae, may be indicated. The more frequent injuries are in the lower lumbar and in the lower cervical regions.

Treatment of a herniated disk in the neck and in the lumbar region continues to be a challenging field of medicine. The classical treatment for a ruptured disk is diskectomy, i.e., removal of the disk from between the vertebrae. In this process, all or a portion of the intervertebral disk is removed, leaving a defect which continues to bother the patients throughout the rest of their lives. An additional procedure is to replace the disk space with a bone graft, usually bone chips cut from the patient's iliac crest, bringing about fusion of the vertebrae above and below the disk, eliminating the empty space between the vertebrae.

Diskectomy with fusion is not ideal because the replaced bone does not have the function of the cartilaginous tissue of the disk, i.e. no cushioning effect, and has complications because of several factors. First, conventional bone plugs used to pack the disk space do not conform to the space of the disk because the disk bulges maximally in the center. The disk space is wider in the middle and narrower at its anterior and posterior ends. For this reason, the various bone plugs which are currently available commercially have only four contact points, i.e. at the front and back of the disk space. Secondly, access to the disk is from the side of the dorsal spine of the adjacent vertebrae, leaving a space that is "off-center" relative to the bodies of the adjacent vertebrae such that the stability of the implant is even more problematical than might be apparent from the limited contact resulting from the shape of the intervertebral space. Another

complication is the possibility of infection or other conditions which may require the removal of the implant. Also, if the bone pieces do not fuse, they may eventually extrude out of the disk space, causing pressure on the nerve roots.

Various prosthetic disk plugs, or implants, are disclosed in the art, but all are characterized by limitations of not conforming to the shape of the disk space, lack of stability when inserted off-center, inability to be removed, or other disadvantages. For instance, U.S. Patent No. 4,863,476 (and its European counterpart, EP-A-0260044) describes an elongated body divided longitudinally into two portions having a cam device movable therebetween for increasing the space between the two body portions once inserted into the disk space. However, that device is generally cylindrical in shape such that the only contact points between the device and the vertebral bodies are at the front and back of the disk space, creating increased likelihood of instability and generally rendering that device unsuitable for use after partial diskectomy. The art also discloses intervertebral disk prostheses (e.g., U.S. Patent Nos. 3,867,728, 4,309,777, 4,863,477 and 4,932,969 and French Patent Application No. 8816184) which may have more general contact with the adjacent disks, but which are not intended for use in fusion of the disks. The art also includes spinal joint prostheses such as is described in U.S. Patent No. 4,759,769, which is again not indicated for use when fusion is the preferred surgical intervention.

There is, therefore, a need for a device capable of stabilizing the vertebrae adjacent an intervertebral disk, but which is also removable, for use in spinal fusion. There is also a need for a method of implanting such a stabilizer.

These needs are met in the present invention by providing a vertebral disk stabilizer comprised of a generally cylindrical, elongate implant having end and middle portions, the middle portion having a diameter larger than the diameter of the end portion, threads formed on the outside surface of the implant for bearing against the bodies of the adjacent vertebrae when the implant is inserted into the anatomical region from which a portion of the intervertebral disk has been removed, and an applicator. The applicator is mounted to the implant for (1) facilitating the insertion of the implant into the region

between the adjacent vertebrae from which the portion of the disk has been removed and (2) rotating the implant so as to cause the implant to move in an anterior-posterior direction as the threads bear against the bodies of the adjacent vertebrae to a position in which both the middle and end portions of the implant engage the bodies of the adjacent vertebrae to support the upper vertebrae, thereby stabilizing the adjacent vertebrae, and is subsequently detached therefrom.

The present invention also provides an apparatus for spreading adjacent vertebrae which is of particular use in conjunction with the above-described vertebral disk stabilizer. The apparatus comprises a handle and an elongate implant portion mounted to the handle. The implant portion, rather than having the substantially cylindrical shape of the implant of the above-described stabilizer, has a substantially rectangular cross-sectional shape. The rectangular shape allows the minimizing of the height of the implant portion, which facilitates insertion through the relatively small space created at the side of the dorsal spine of the adjacent vertebrae after laminotomy, while the width of the implant portion is maximized so that when the implant portion is rotated 90° in the disk space by rotation of the handle, the adjacent vertebrae are spread apart.

Also provided is a method of stabilizing adjacent vertebrae, particularly lumbar vertebrae, comprising the steps of spreading two adjacent vertebrae and removing a portion of the intervertebral disk from therebetween followed by insertion of an elongate, generally cylindrically shaped implant having middle and end portions, the middle portion being of larger diameter than the end portion, into the space between the adjacent vertebrae from which the disk has been removed. The implant is then rotated to cause threads formed on the outside surface thereof to bear against the bodies of the adjacent vertebrae to move the implant in an anterior-posterior direction until positioned at a point between the adjacent vertebrae at which both the larger diameter middle portion and the smaller diameter end portion of the implant engage the vertebrae to stabilize the adjacent vertebrae relative to each other.

Referring now to the figures, Figure 1 is a plan view of a preferred embodiment of a vertebral disk stabilizer constructed in accordance with the present invention.

Figure 2 is a projected view of the applicator of the stabilizer of Fig. 1 after being detached from the implant.

Figure 3 is a projected view of the implant of the stabilizer of Fig. 1 after being detached from the applicator.

Figures 4A, 4B, and 4C are plan, side, and cross-sectional views, respectively (Fig. 4C being taken along the lines 4C-4C in Fig. 4A), of a spreader which is used to advantage in connection with the insertion of the implant of the stabilizer of Fig. 1 between two adjacent vertebrae of a patient's spinal column.

Figure 5 is a plan view of a second embodiment of a spreader which is constructed in accordance with the present invention.

Figure 6 is a lateral view of a portion of a human spinal column having the implant of the stabilizer of Fig. 1 inserted therein and having a portion of the bodies of the vertebrae adjacent the implant shown cut away to show the engagement of the vertebral bodies by the implant.

Figures 7A and 7B are plan and longitudinal sectional views respectively, of a third embodiment of the stabilizer of the present invention.

Figure 8 is a plan view of the implant of the stabilizer of Fig. 7A after being detached from the applicator.

Figure 9 is a plan view of a second embodiment of a stabilizer constructed in accordance with the present invention.

Figure 10 is a projected view of the applicator of the stabilizer of Fig. 9 after detaching the implant therefrom.

Figure 11 is a projected view of the implant of the stabilizer of Fig. 9 after being detached from the applicator.

Figure 12 is a longitudinal, sectional view of a portion of the stabilizer of Fig. 9, taken along the lines 12-12 in Fig. 9.

Figure 13 is a projected view of another embodiment of an implant constructed in accordance with the present invention and which is used in place of the implant of Fig. 3.

Figure 14 is an exploded, projected view of another embodiment of a stabilizer constructed in accordance with the present invention.

Figure 15 is a plan view of a third embodiment of a spreader which is preferably used to advantage in connection with insertion of the implant portion of the stabilizer of Fig. 14 between two adjacent vertebrae of a patient's spinal column.

A first embodiment of the stabilizer of the present invention is described in more detail by referring to Fig. 1, showing a stabilizer which is indicated generally at reference numeral 10 and which comprises two parts, an applicator 12 and an implant 14. Applicator 12 is shown with a handle 16 in the shape of a "T", but the handle 16 may take the form of any convenient hand grip or other structure which facilitates the handling of the stabilizer 10 and subsequent rotation of the stabilizer 10 once the implant 14 has been inserted into the space between two adjacent vertebrae as more particularly described below.

As shown more clearly when Fig. 1 is viewed in conjunction with Figs. 2 and 3, applicator 12 is comprised of an elongate shaft 18 having a longitudinal bore 20 therethrough, the bore 20 terminating in a point, with an elongate piston 22 disposed therein. Piston 22 is provided with a wedge-shaped, or pointed, end 24 which is sized to approximate the shape of the pointed end of the bore 20 in shaft 18 at one end and a handle 26 formed at the other end. As best shown in Fig. 2, the end 28 of shaft 18 is provided with screw threads 30 which mate with the threads 32 (see Fig. 3) formed in the interior wall of the bore 34 in implant 14. In this manner, the end 28 of shaft 18 is received in and affirmatively engages the implant 14 to detachably mount implant 14 to applicator 12. Applicator 12 is provided with means for preventing relative rotational movement between the implant 14 and applicator 12 comprised, in the embodiment shown, of a plurality of radially spaced, longitudinal slots 36 in the end 28 of shaft 18 communicating with the longitudinal bore 20 therethrough and the wedge-shaped end 24 of piston 22. When piston 22 is forced down into the bore 20 in shaft 18, the pointed end 24 of piston 22 acts to spread, or force the portions 38 of the threaded end of shaft 18 between slots 36 outwardly into increasingly tighter frictional engagement with the interior wall of the bore 34 of implant 34, thereby preventing relative rotational movement of the implant 14 and applicator 12.

Implant 14 is formed in the shape of a generally elongate cylinder with a blunt, or rounded end 40 and an end 42 having the aforementioned bore 34 opening therein. The diameter of the ends 40 and 42 is smaller than the diameter of the middle portion 44 of the implant for a purpose to be explained below. The outside surface of implant 14 is provided with threads 46, the function of which is also set out below. Implant 14 is preferably constructed of any durable, relatively biologically inert substance such as carbon fiber, titanium, several medical grade hard plastics, and such other materials as are known in the art for use in such implants.

Referring now to Figs. 4 and 5, there is shown a spreader, indicated generally at reference numeral 48, having integral handle 50 and implant 52 portions. As shown in Figs. 4A, 4B, and 4C, although the shaft of the handle 50 of spreader 48 is substantially round in cross section and the elongate implant portion 52 is mounted on the end thereof, the cross-sectional shape of the implant portion 52 is substantially rectangular. In other words, opposed sides of the handle 50 are flattened at the end to which the implant portion 52 of spreader 48 is mounted. In this manner, the dimension of the implant portion 52 which represents the height (indicated at H on Figs. 4B and 4C) of the rectangular cross-section is minimized and the dimension of the implant portion 52 which represents the width (indicated at W on Figs. 4A and 4C) of the rectangular cross-section is maximized. The minimal dimension H facilitates insertion of the implant portion 52 into the disk space between two adjacent vertebrae through the small anterior-posterior opening between vertebrae and at the side of the dorsal spine which results from a laminotomy. After insertion of the implant portion 52 through that opening, the implant portion 52 is rotated by rotation of handle 50 so that the maximal dimension W of the implant portion 52 causes maximal spreading, or distraction, of the adjacent vertebrae. As best shown in Fig. 4C, the portions 49 of the implant portion 52 of spreader 48 which form the corners of the substantially rectangular cross-section thereof are rounded for reducing the resistance to rotation of the implant portion 52 The rounded corners 49 therefore effectively act as ramps conferring mechanical advantage on the implant portion 52 when rotated.

By reference to Fig. 4A, it can also be seen that the width of the maximal dimension W of the implant portion 52 of spreader 48 is greater in the middle portion 51 of the implant portion 52 than at the ends 53A and 53B of the implant portion 52. Further, the width of the maximal dimension W is greater at one end 53A of implant portion 52 than at the other end 53B, the end 53A being mounted to handle 50. This shape of implant portion 52 further reduces the resistance to rotation, distributes the force exerted against the bodies of the adjacent vertebrae that results from rotation over more surface area of the bodies of the adjacent vertebrae, and helps retain the implant portion 52 therebetween until it is desired to remove it from the disk space. The end 53B of implant portion 52 which is the end inserted first into the disk space is rounded to facilitate insertion and reduce the likelihood and severity of unintended trauma during insertion. The smaller maximum dimension W at the end 53B functions in similar fashion and the slope between the end 53B and middle portion 51' further facilitates introduction of structure having the maximal dimension W into the disk space.

A second embodiment of the spreader of the present invention is indicated generally at reference numeral 48' in Fig. 5. This second embodiment 48' is provided with a handle 50' and an implant portion 52' that is sized and generally cylindrically-shaped in the same size and dimensions as the implant 14 of stabilizer 10 and is used in the following manner.

The use of the stabilizer 10 of the present invention in, for instance, a method of lumbar interverbral disk stabilization, or "LIDS", is illustrated in Fig. 6. Surgery is performed as in a simple diskectomy and the intervertebral disk 54 is exposed through a small laminotomy. The disk material is removed and any nerve root compression is corrected. The posterior longitudinal ligament and disk cartilage are removed until the surfaces of the bodies 60 and 62 of adjacent vertebrae 56 and 58, respectively, are exposed above and below the disk space.

Using either of the spreaders 48 or 48', the vertebrae 56 and 58 are distracted to open the disk space, and once the desired "spread" has been achieved, the middle portion of the disk space is packed with cancellous bone chips (not shown). As described below, a kit of

several spreaders, each having progressively larger diameter implant portions, is used to achieve the desired spread. Because the posterior longitudinal ligament is left intact to the opposite side and to the center of the disk space, the bone chips are held in place in the disk space. The appropriately-sized implant 14 of stabilizer 10 is then inserted into the disk space using the applicator 12 until the threads 46 formed on the outside surface of implant 14 engage the bodies 60 and 62 of the adjacent vertebrae 56 and 58, respectively. Piston 22 is then wedged into the bore 20 to cause the applicator 12 to frictionally engage implant 14 to prevent relative rotational movement therebetween and the stabilizer 10 is rotated. Rotation of the implant 14 in the disk space causes the threads 46 to bear against the bodies 60 and 62 to move the implant further into (or back out of, depending upon the direction of rotation) the disk space in an anterior-posterior direction so as to enable the implant 14 to be positioned in the disk space at a position in which the expanded, or larger diameter portion 44 and the smaller diameter ends 40 and 42 of implant 14 contact the respective lower and upper surfaces of the bodies 60 and 62 of the adjacent vertebrae 56 and 58. The respective lower and upper surfaces of the vertebral bodies 60 and 62 are slightly concave such that the expanded middle portion 44 of implant 44 allows the implant 14 to engage substantially more of the respective surfaces of the vertebral bodies 60 and 62 than conventional prosthetic devices, thereby providing increased stability to the fusion.

Once positioned in the disk space so as to provide maximum stabilization, pressure on the piston 22 is released and the piston 22 is backed out of the bore 34 so as to allow the applicator 12 to be rotated without rotating the implant 14. The applicator is then detached from the implant 14 by unscrewing and backed out of the incision. If necessary, a small amount of physiologically compatible adhesive is applied over the cancellous bone chips just medial to the implant to close off the remaining portion of the opening into the disk space. The patient should be able to ambulate soon after the LIDS procedure because of the stability imparted to the spinal column by the implant of the present invention. Before narrowing of the disk space occurs, the cancellous bone chips will have started the fusion process.

The stabilizer 10 is also used to advantage to perform, for instance, a posterior lateral intertransverse fusion. The implant 14 is inserted into the region of the disk space from which a portion of the disk has been removed as described above and the posterior lateral fusion performed. Because the implant 14 provides stability to the spine until the posterior lateral fusion is solid, the patient is generally able to ambulate soon after surgery. This procedure also prevents the narrowing of the disk space, which is a common problem with posterior lateral fusion.

Removal of the implant 14 is accomplished with relative ease compared to conventional implants. The shaft 18 of applicator 12 is screwed back into the threaded bore 34 in implant 14, piston 22 is re-inserted into the longitudinal bore 20 in applicator 12, and by applying pressure to piston 22 to prevent relative rotation between implant 14 and applicator 12, the implant is rotated to cause posteriorly-directed movement of the implant 14 out of the disk space.

Referring now to Figs. 7A, 7B, and 8, a second embodiment of the stabilizer of the present invention is comprised of an applicator 13 (Fig. 7A) and an implant 15 (Fig. 7B), the implant 15 being mounted on the end of applicator 13 as will be described. Applicator 13 is comprised of an elongate shaft 19 having a longitudinal bore 21 therethrough with an elongate mandrel 23 disposed therein. Mandrel 23 is provided with an end 25 having screw threads 31 formed thereon which mate with the screw threads 33 (see Fig. 7B) formed in the interior wall of the bore 35 in implant 15. In this manner, the end 25 of mandrel 23 is received in and affirmatively engages the implant 15 to detachably mount implant 15 to applicator 13.

Implant 15 is detached from the applicator 13 by rotating mandrel 23, causing the mandrel 23 to back out of bore 21 as a result of the engagement of the threads 29 formed thereon with the threads 37 formed in the wall of the bore 21 in applicator 13, until the end 27 of the implant 15 contacts the end 39 of applicator 13. The friction resulting from that contact prevents further rotation of implant 15 and as a result of the continued rotation of mandrel 23, the implant 15 is detached therefrom.

Referring to Figs. 7B and 8, the implant 15 is shown in detail. Implant 15 is constructed and functions as described in International Application No. PCT/US92/01397 (WO 92/14423) and so is described only briefly here. The implant 15 is formed in the shape of a generally elongate, hollow cylinder comprised of a flexible plastic, metal, or similar medically inert material of the type described above with a screw 41 positioned in the threaded bore 35 therethrough. Also positioned in the bore 35 is a jam nut 43 which is formed in the shape of a ring to allow access to the screwdriver slot formed in the head 45 of screw 41 and which is itself provided with a slot 47 for receiving a screwdriver (not shown). Upon rotation of screw 41, the ends of implant 15 are drawn towards each other, causing expansion of the middle portion thereof. Referring again to Fig. 7A, it can be seen that the mandrel 23 positioned in applicator 23 is provided with a bore B for receipt of a screwdriver therethrough to facilitate rotation of screw 41. Once sufficient expansion is achieved, a second screwdriver replaces the first for rotation of jam nut 43 against the head 45 of screw 41, thereby preventing further rotation. The end of implant 15 is rounded and provided with threads T in the same manner and for the same purposes as implant 14. Once the jam nut 43 is tightened against the head 45 of screw 41, the screwdriver slot 47 in jam nut 43 and the slot in the head 45 operate in conjunction with the threads T on the outer surface of implant 15 to allow fine positioning of the implant 15 in the disk space.

Referring now to Figs. 9-12, another embodiment of the stabilizer of the present invention is indicated generally at reference numeral 64. Stabilizer 64 is comprised of applicator 66 and implant 68 portions having the same general function and component parts as those of the stabilizer 10 shown in Figs. 4, 7 and 8. However, the shaft 70 of applicator 66, rather than being provided with a bore having a piston disposed therein as with the bore 20 and piston 22 of the stabilizer 10, is provided with a hole 72 near the end in which the handle 74 is formed and a longitudinal groove 76 crossing the threads 78 formed in the end of shaft 70 which is received by the threads 80 in the bore 82 of implant 68. A similar groove 84, best shown in Fig. 9, runs longitudinally across the threads 80 in the bore 82 of implant 68. A safety line, or wire, 86 is threaded through the hole 72 in shaft

70 having a wedge-shaped key 88 attached to the other end thereof and, when the implant 68 is mounted to the shaft 70 of applicator 66 and the grooves 76 and aligned, key 88 is wedged into the key slot formed by the aligned grooves 76 and 84 by insertion into the portion 90 of the groove 76 formed at the end of the shaft 70 which extends beyond the smaller diameter end portion 92 (compared to the diameter of the expanded middle portion 94) of implant 68, the applicator 66 and implant 68 are locked up to prevent relative rotation therebetween so that the threads 96 formed on the external surface of implant 68 function in the same manner and for the same purpose as described in connection with the stabilizer 10.

In certain applications, for instance, when fusion is being performed on a patient having deteriorating vertebrae, it may be desirable to have threads formed at more than one location on the external surface of the implant. In such circumstances, an implant such as the implant indicated at reference numeral 98 in Fig. 13 is utilized in connection with the applicator 12 shown in Figs. 1-4 or 7 (implant 98 may also be provided with a groove such as the groove 84 in the implant 68 of Figs. 9-12 for use in connection with the applicator 66). Implant 98 is provided with two sets of threads 100 formed on the external surface thereof to increase the likelihood that the threads 100 will bear against the bodies of the vertebrae between which it is inserted to facilitate the anterior-posterior positioning of the implant 98 in the anatomical region of the disk space.

Referring now to Fig. 14, there is shown yet another embodiment of a disk stabilizer, indicated generally at reference numeral 102, constructed in accordance with the present invention. Stabilizer 102 is comprised of an applicator 104 and implant 106 being detachably mounted to applicator 104 by receipt of the keys 108 formed in the smaller diameter end portion 110 (compared to the expanded middle portion 112) of implant 106 by the T-slots 114 formed at the end of the shaft 116 of applicator 104 opposite handle 118. To provide additional rigidity to the mounting of implant 106 to applicator 104, the end 110 of implant 106 is provided with a cylindrical extension 120 which is received within a similarly dimensioned cavity 122 formed on the end of shaft 116, the external

surface of extension 120 bearing against the inside wall of the cavity 122 to stabilize the implant 106 on the end of applicator 104.

Implant 106 is, like each of the implants 14, 15, 68, and 98, formed in the shape of a generally elongate cylinder having end 110 and 124 and middle 112 portions, the diameter of the middle portion 112 being larger than the diameter of the end portions 110 and 124. In the case of the implant 106, however both ends 110 and 124 are provided with threads on the external surface of the implant and the larger diameter middle portion 112 is not located in equidistant from the ends 110 and 124. Instead, the largest diameter of the implant 106 is located closer to the end 110 of the implant 106 which is located posteriorly when inserted into the disk space such that the slope of the external surface 126 between the largest diameter of the middle portion 112 and end 110 is greater than the slope of the external surface 128 of implant 106 between the middle portion 112 and end 124. By shaping implant 106 in this manner, the increased slope of the surface 126 helps to prevent undesirable posterior movement of the implant 106 in the disk space once inserted. To decrease any tendency of the implant 106 to move in the anterior direction, the diameter of the end portion 124 of implant 106 is optionally larger than the diameter of the end portion 110. As is the case with each of the implants 14, 15, 68, and 98, the end 124 of implant 106 is formed in a blunt, or rounded, shape to reduce the likelihood of injury to the nerves of the spinal cord during insertion into the disk space. To further facilitate proper anterior-posterior positioning of the implant 106 in performing the above-described LIDS procedure, the surface of the extension 120 at the end 110 of implant 106 is provided with a slot 130 for receiving a screwdriver blade (not shown) for fine adjustment of the position in the disk space.

A spreader, indicated generally at reference numeral 132 in Fig. 15, is provided for spreading the adjacent vertebrae for insertion of the implant 106. Spreader 132 is formed of an integral handle 134 and implant portion 136, the latter being formed in the same approximate shape as the implant 106 of stabilizer 102.

It is advantageous to provide a kit comprised of a number of spreaders 48, 48' or 132, depending upon the particular stabilizer 10,

11, 64, or 102 being employed, of progressively larger diameters to obtain the desired degree of spread of the vertebrae adjacent the disk space into which the implant 14, 15, 68, 98, or 106 is to be inserted. The kit of spreaders are of increasingly larger diameters (for instance, 6, 8, 10, and 12 mm or, in the case of spreader 48, it is the maximal dimension W which is sized to these dimensions) in their respective expanded middle portions; it is also advantageous to supply spreaders in the kit having implant portions of different lengths. Likewise, it is advantageous to include implants in the kit of different diameters and lengths to obtain the best fit between the anatomical region of the disk space into which the implant is being inserted and the shape of the implant so as to be able to position the implant in the disk space at which the largest proportion of the external surface of the implant bears against the surfaces of the bodies of the adjacent vertebrae, thereby maximizing the stabilizing properties of the implant.

Although described in terms of the several embodiments shown in the figures, those embodiments are shown to exemplify the present invention, it being recognized that certain changes can be made to the specific structure of these various embodiments shown and described without departing from the present invention. For instance, there are many ways other than those illustrated to mount the implant to the applicator so as to selectively prevent relative rotation therebetween while still enabling the applicator to be detached from the implant once positioned in the disk space. Likewise, the implant is described herein as being "generally cylindrical" in shape, but additional stability may be obtained by forming the implant with a slightly ovoid, or elliptical, cross-sectional shape while retaining the elongate, generally cylindrical shape of the implant. In the case of an implant such as is contemplated in the case of the stabilizer of Figs. 1-5 but having a "flattened" cross-sectional shape, it will be recognized that the grooves 76 and 84 in the applicator 66 and implant 68, respectively, are aligned with both the handle 74 of applicator 66 and either the minimum or the maximum dimension of the cross-sectional shape of the implant to facilitate rotation of the implant in the disk space so as to enable the maximum surface area of the implant (e.g., the flattened" surface) to bear against the bodies of the respective adjacent vertebrae.

WHAT IS CLAIMED IS:

1. A vertebral disk stabilizer comprising:

a generally cylindrical, elongate implant having end and middle portions, the middle portion having a diameter larger than the diameter of the end portion;

threads formed on the outside surface of said implant for bearing against the bodies of the adjacent vertebrae when said implant is inserted into the anatomical region from which a portion of the intervertebral disk has been removed; and

an applicator detachably mounted to one end of said implant for (a) inserting said implant into the region from which a portion of the intervertebral disk has been removed, (b) rotating said implant so as to cause said threads to move said implant in an anterior-posterior direction to a position in which the bodies of the adjacent vertebrae engage both the middle and the end portions of said implant to support and stabilize the adjacent vertebrae, and (c) subsequent detachment therefrom.

2. The stabilizer of claim 1 wherein said implant is detachably mounted to said applicator by threads formed on the end of said applicator for mating with a set of threads formed on the end of said implant.

3. The stabilizer of claim 2 additionally comprising means for preventing relative rotation between said applicator and said implant.

4. The stabilizer of claim 1 wherein the middle portion of said implant is expandable from a first diameter approximately equal to the diameter of the end portions of said implant to a second, larger diameter after insertion of said implant into the region from which a portion of the intervertebral disk has been removed.

5. A kit including the stabilizer of claim 1 and a spreader for use in connection therewith, the spreader being comprised of a handle having an implant portion mounted thereto.

6. The kit of claim 5 wherein the implant portion of said spreader is shaped and sized in approximately the same size and shape as the implant of the stabilizer.

7. The kit of claim 5 additionally comprising a plurality of spreaders having implant portions of progressively larger diameters.

8. A spreader for insertion into the disk space between adjacent vertebrae from the side of the dorsal spine after laminotomy comprising a handle and an elongate implant portion mounted to said handle, said implant portion having a substantially rectangular cross-sectional shape, the rectangular cross-sectional shape being minimized in height to facilitate insertion of said implant portion into the disk space and maximized in width for rotation by approximately 90° by rotation of said handle after insertion into the disk space to spread the vertebrae adjacent the disk space apart from each other.

9. The spreader of claim 8 wherein the corners of the substantially rectangular cross-sectional shape of said implant portion are rounded to facilitate rotation of said apparatus after insertion of said implant portion into the disk space.

10. The spreader of claim 8 wherein the width of said implant portion is greater in the middle portion than at the ends thereof.

11. The spreader of claim 10 wherein the width of said implant portion is greater at one end of said implant portion than at the other.

12. The spreader of claim 11 wherein said implant portion is mounted to said handle at the end of said implant portion having the greater width.

13. A kit including a plurality of the spreaders of claim 8, each of said plurality of spreaders having an implant portion of progressively larger width, for insertion into and removal from the disk space in sequential fashion until the adjacent vertebrae are spread to a desired degree.

14. A method of intervertebral disk stabilization comprising the steps of:

spreading adjacent vertebrae;

removing a portion of the intervertebral disk from between the adjacent vertebrae;

inserting an elongate, generally cylindrically shaped implant having middle and end portions, the middle portion being of larger diameter than the end portion, into the space between the adjacent vertebrae from which a portion of the disk has been removed; and

rotating the elongate implant to cause threads formed on the outside surface thereof to bear against the bodies of the adjacent vertebrae to move the implant in an anterior-posterior direction to a position between the adjacent vertebrae at which both the larger diameter middle portion and the smaller diameter end portion of the elongate implant engage the bodies of the adjacent vertebrae to stabilize the adjacent vertebrae relative to each other.

15. The method of claim 14 additionally comprising detaching the applicator from the elongate implant.

16. The method of claim 14 wherein the elongate implant is mounted to the applicator on threads and the applicator is detached from the elongate implant by rotating the applicator relative to the elongate implant after insertion of the elongate implant.

17. The method of claim 16 additionally comprising rotating the applicator to position the elongate implant.

18. The method of claim 17 additionally comprising preventing relative rotation of the elongate implant and the applicator during the positioning of the elongate implant.

19. The method of claim 14 additionally comprising preventing anterior-posterior movement of the elongate implant after the elongate implant is positioned.

20. The method of claim 14 wherein the adjacent vertebrae are spread by inserting a spreader comprised of a handle and an integral implant portion, the implant portion of the spreader being shaped in a similar shape to the elongate implant, between the adjacent vertebrae.

21. The method of claim 20 additionally comprising sequentially inserting the implant portions of additional spreaders between the adjacent vertebrae, each of the additional spreaders having implant portions of increasingly larger diameters, to spread the adjacent vertebrae progressively further apart.

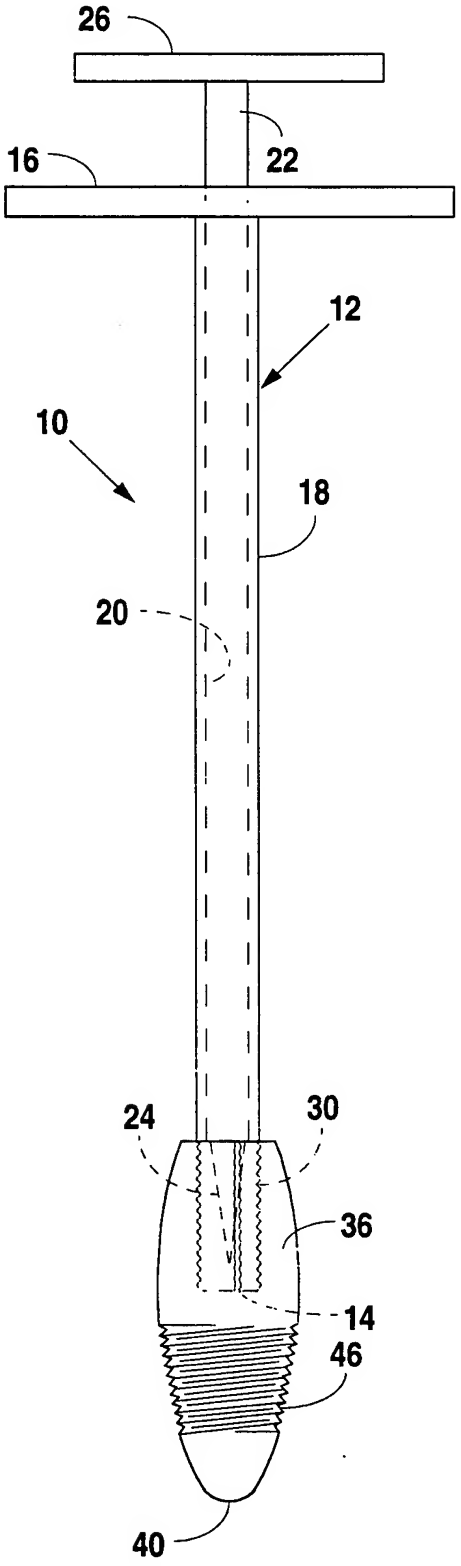

Fig. 1

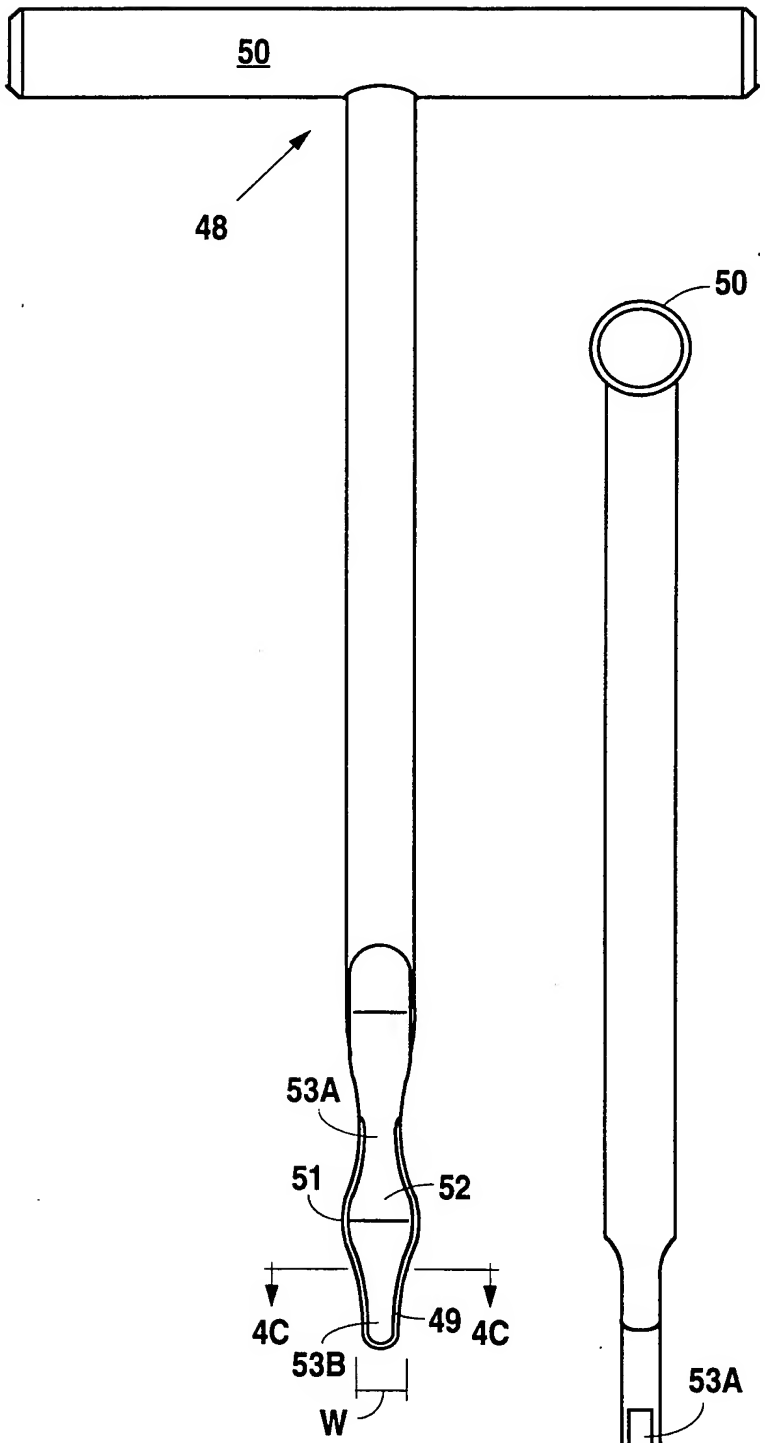

Fig. 4A

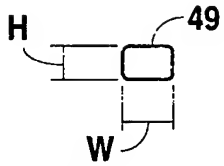

Fig. 4C

Fig. 4B

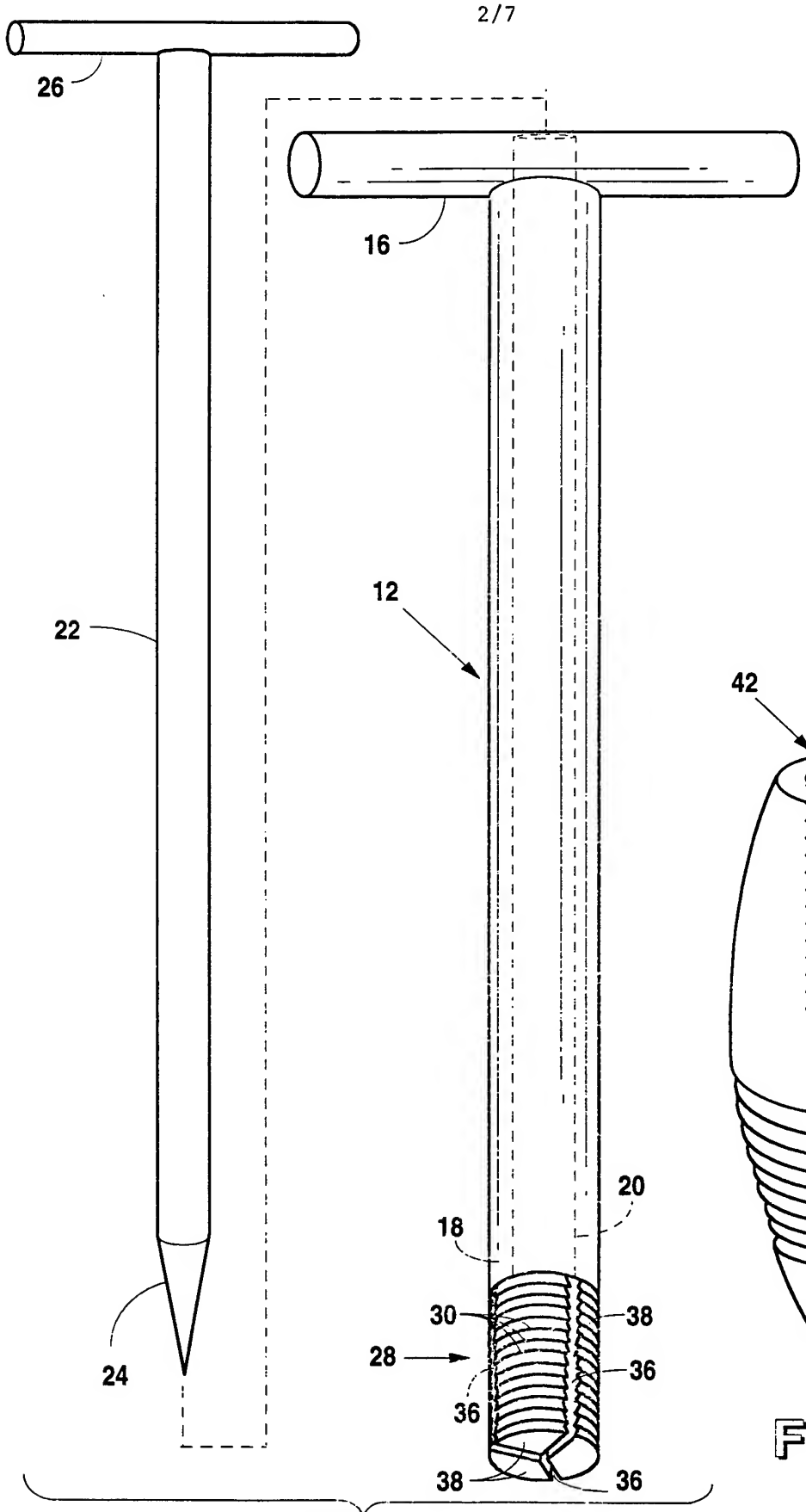

Fig. 2

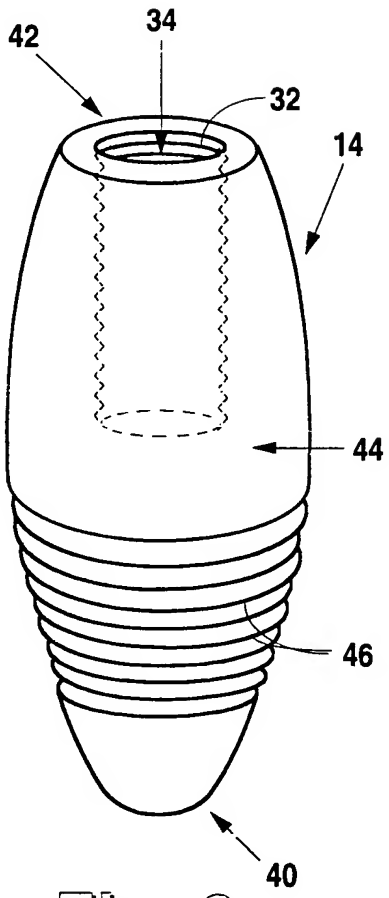

Fig. 3

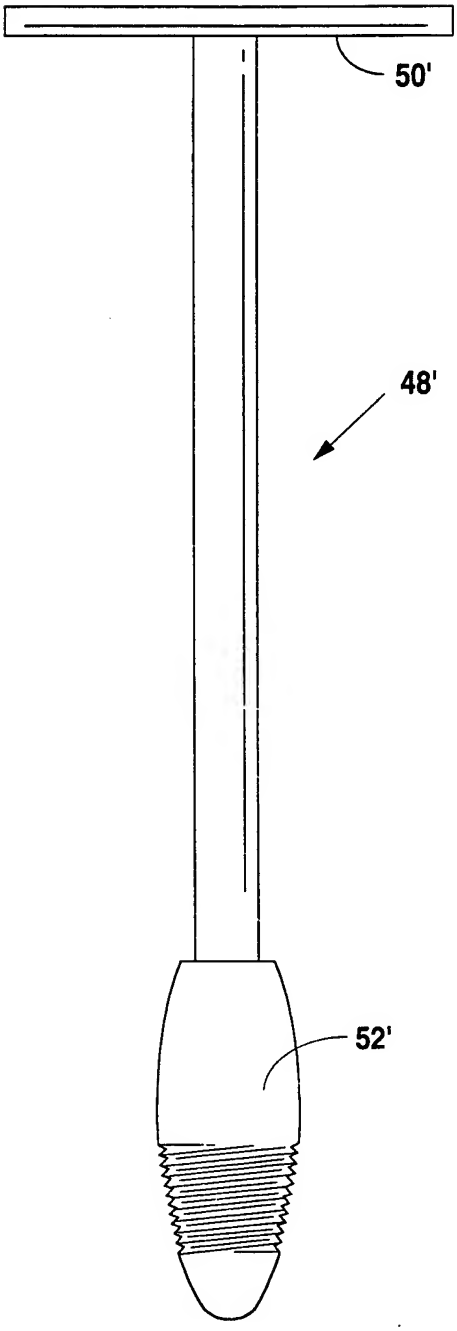

Fig. 5

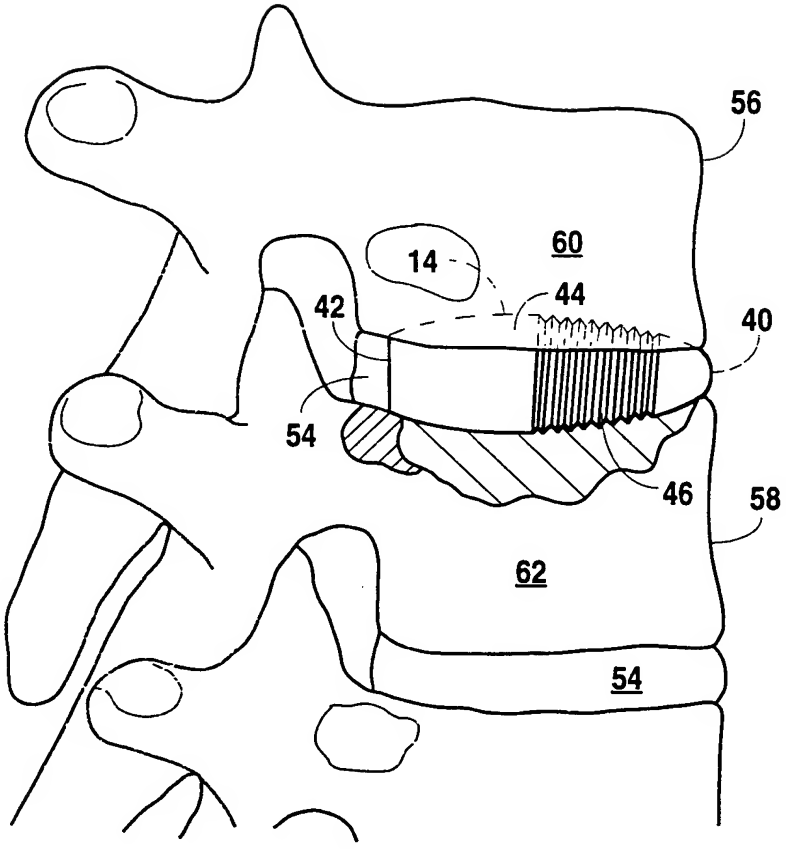

Fig. 6

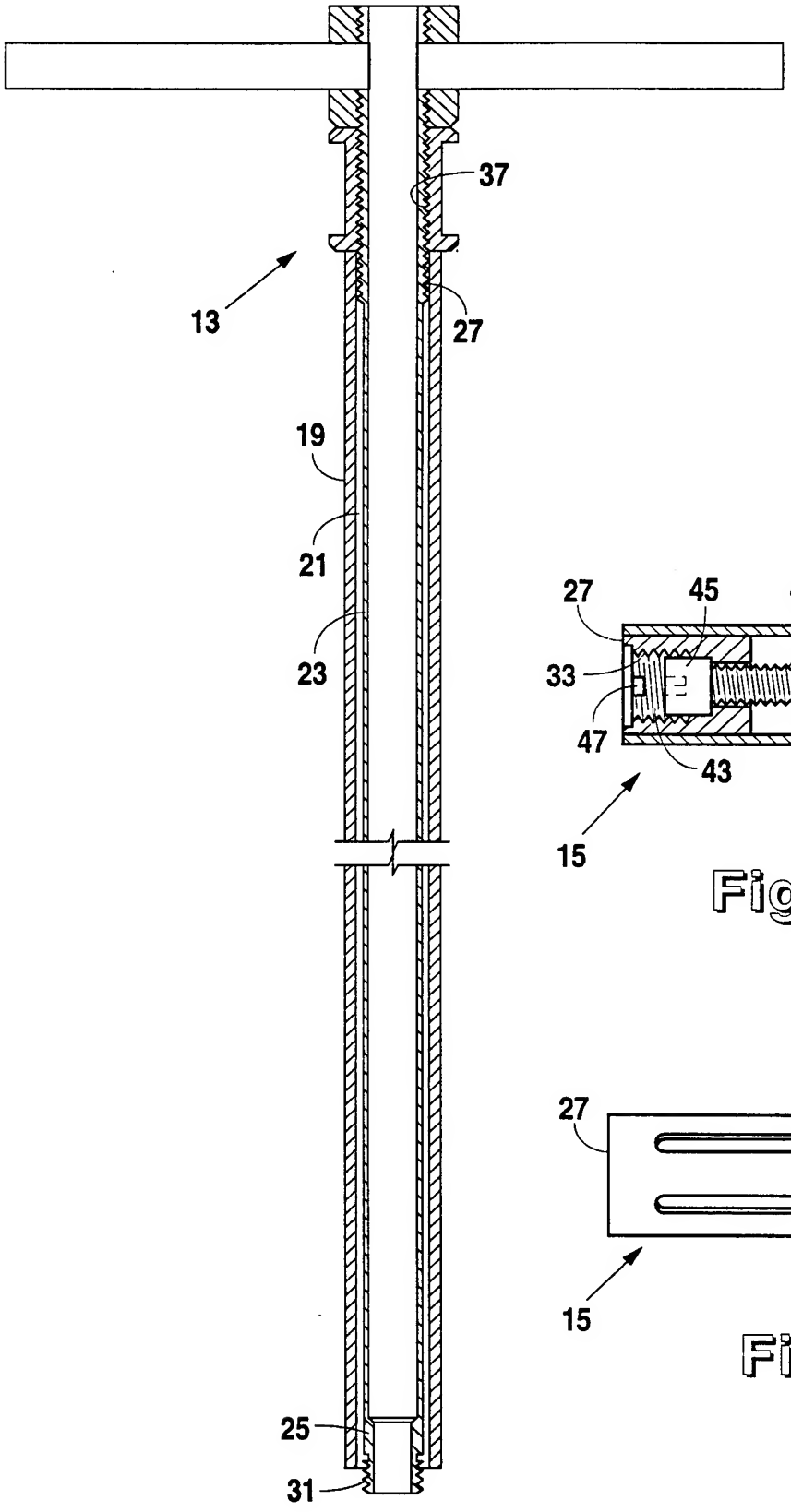

Fig. 7A

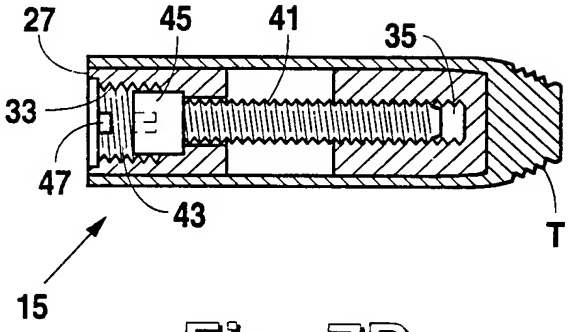

Fig. 7B

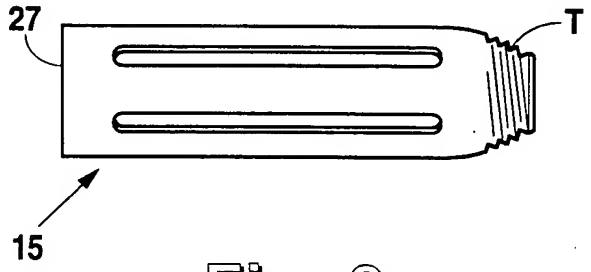

Fig. 8

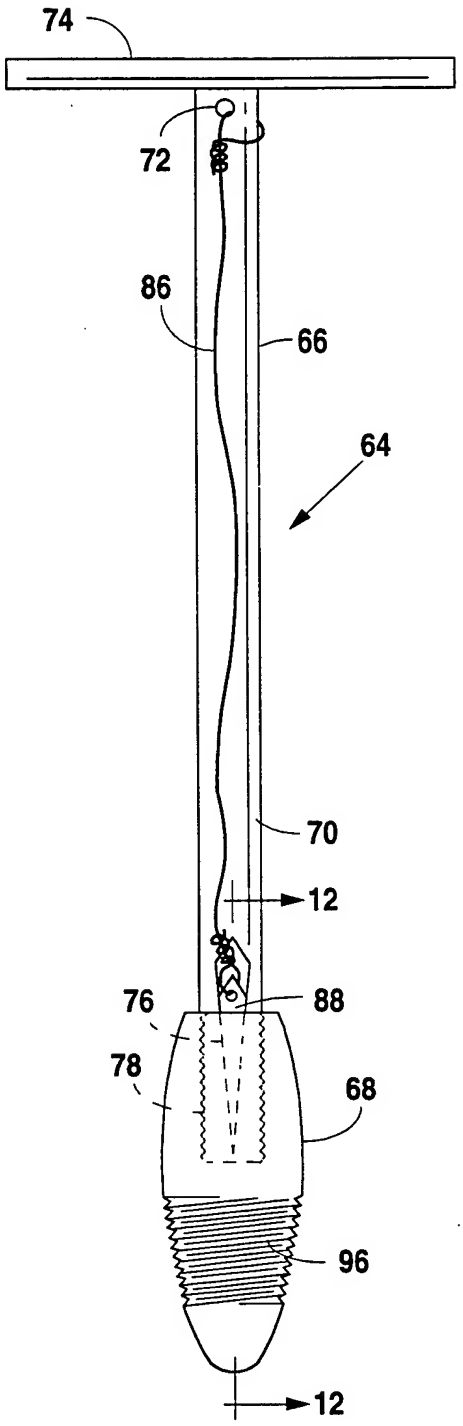

Fig. 9

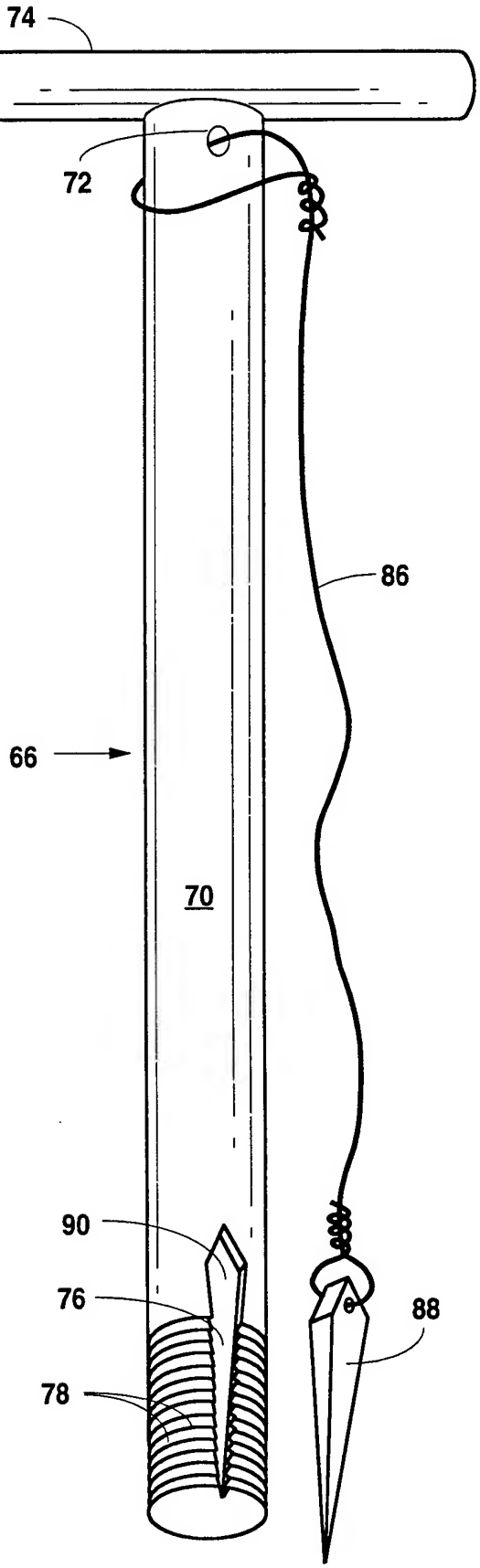

Fig. 10

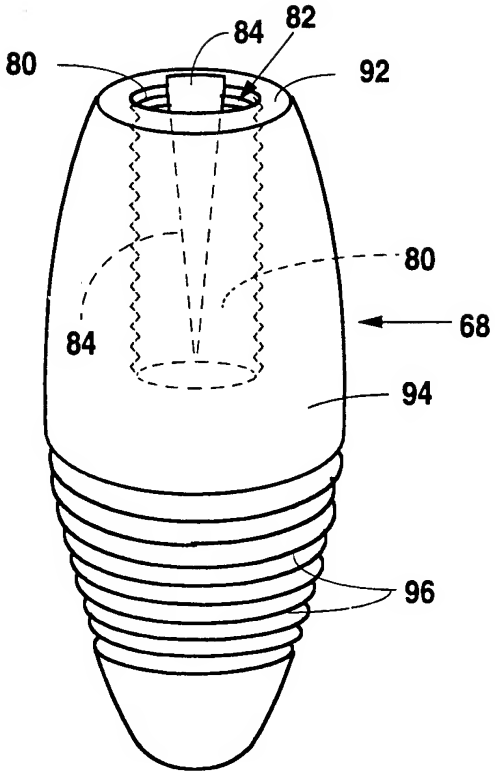

Fig. 11

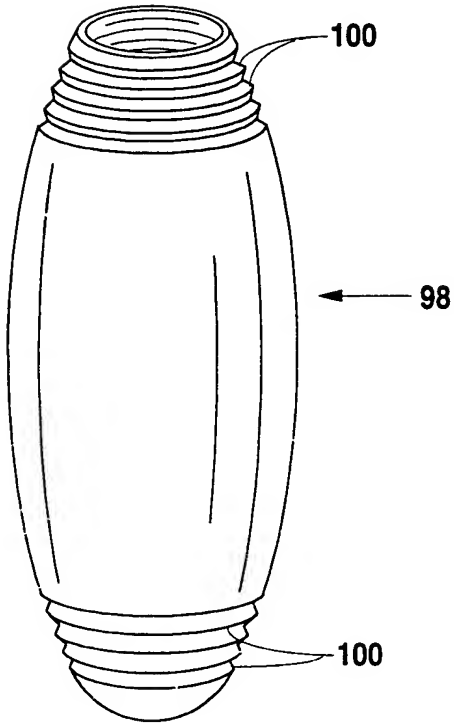

Fig. 13

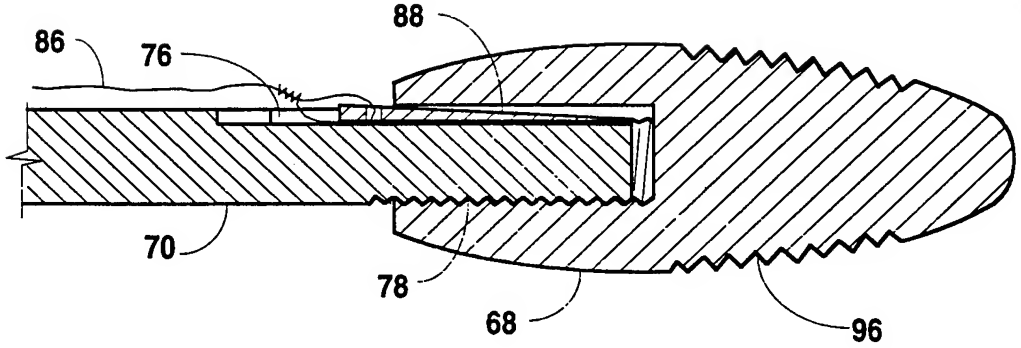

Fig. 12

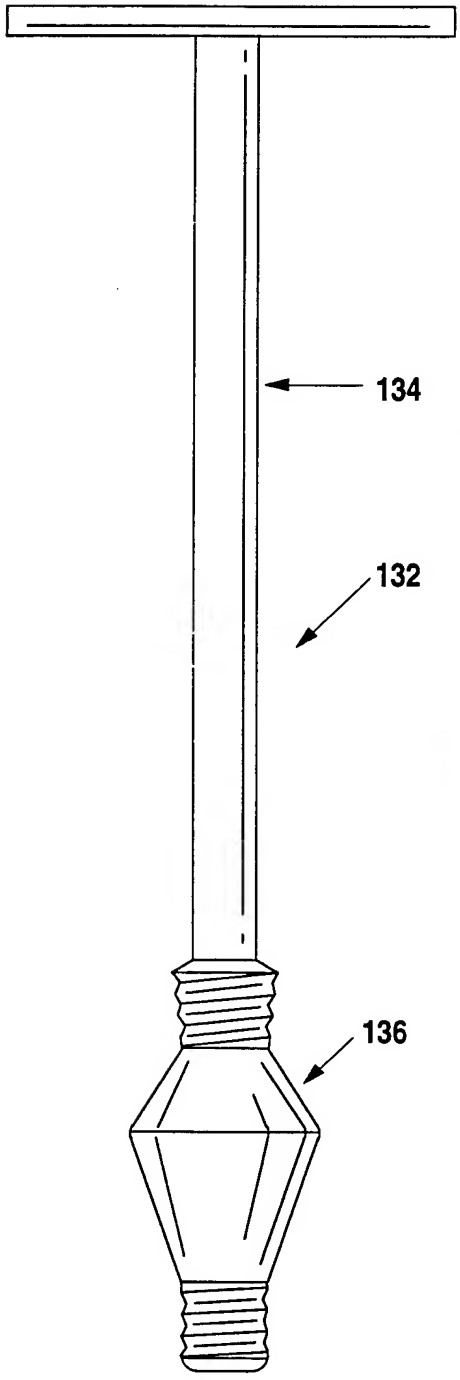
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Fig. 15

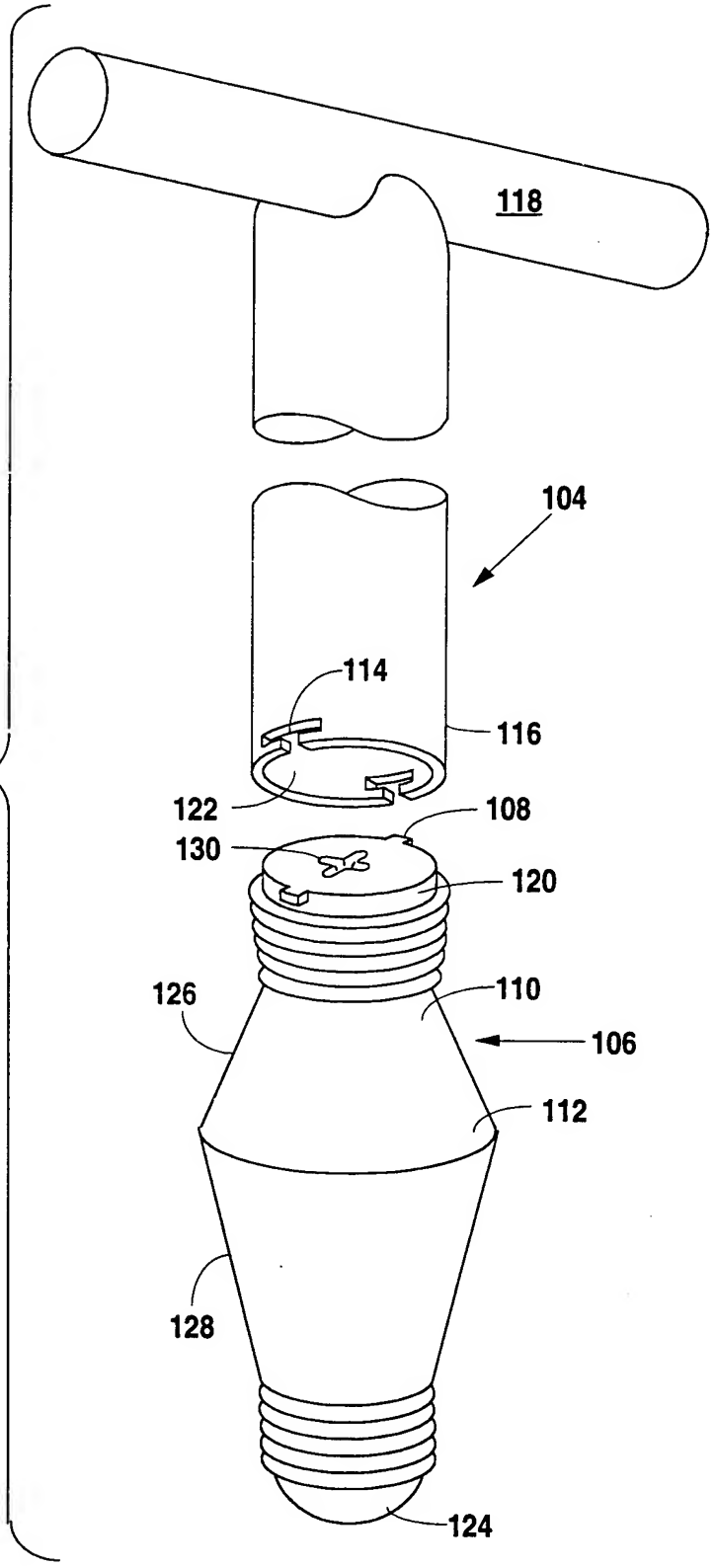
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Fig. 14

INTERNATIONAL SEARCH REPORT

Inte: onal Application No
PCT/US 95/03374

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/44 A61F2/46 A61B17/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP,A,0 042 271 (KUNTZ DAVID J) 23 December 1981 see page 10, line 25 - page 12, line 11; figures see page 13, line 10 - page 14, line 3	1-3,5,6
A	---	8-10
Y	EP,A,0 307 241 (BRANTIGAN JOHN W) 15 March 1989 see column 7, line 63 - column 8, line 9; figures see column 8, line 34 - line 57	1-3,5,6
A	---	1-3
	DE,A,35 05 567 (VICH JOSE MANUEL OTERO DR) 5 June 1986 see page 6 - page 8, paragraph 1; figures	

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 July 1995	03. 08. 95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter. ional Application No
PCT/US 95/03374

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,92 14423 (MADHAVAN PISHARODI) 3 September 1992 cited in the application see abstract; figures 5-7	1,4
A	US,A,3 486 505 (MORRISON GORDON M) 30 December 1969 see figures	8

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

I national application No.
PCT/US95/03374

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 14-21
because they relate to subject matter not required to be searched by this Authority, namely:
Please see Rule 39.1(iv) PCT

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Inter ional Application No
PCT/US 95/03374

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